Braemar, Inc.

DL900 Series Holter Monitor

Operator Manual

Braemar Limited Warranty

Braemar products are warranted to be free from manufacturing and material defects for a period of one (1) year from the date of shipment from Braemar to the original purchaser.

Excluded from this warranty are expendable supply items including, but not limited to, electrodes, leadwires, patient cables and batteries. This warranty does not apply to any product, which Braemar determines has been modified or damaged by the customer.

Except for the express warranties stated above, Braemar disclaims all warranties including implied warranties of merchantability and fitness. The stated express warranties are in lieu of all obligations of liabilities on the part of Braemar for damages, including but not limited to, special indirect or consequential, arising out of or in connection with the use or performance of Braemar products.

Any action for breach of warranty shall be commenced within one (1) year of said breach or be forever barred. Any repairs made to the product that are not covered by the warranty shall be billed to the customer.

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Table of Contents

Description **1**

Indications for Use **1**

Recent DL900 Changes **2**

DL900 Phison SD Card Service Instructions **2**

Monitor Components **3**

Precautions **4**

Electrode Application **5**
- **3-Channel (7-Lead) Electrode Placement** 6
- **3-Channel (5 Lead) Electrode Placement (1st option)** 7
- **3 Channel (5-Lead) Electrode Placement (2nd option)** 8

How to Setup and Record **10**

Monitor Menu Layout and Description **14**

During a recording **22**
- **Patient Event Marker and Reporting Symptoms** 22
- **Early-Out and real time ECG during a recording** 22

Removal of Monitor, Battery and Patient Cable **23**

Analyzing the ECG Data (two options) **24**

Maintenance and Service **26**
- **Cleaning** 26
- **Service Items & Accessories** 27

Troubleshooting **28**

Equipment Symbols **31**

Specifications **32**

Electromagnetic Emissions **33**

Electromagnetic Immunity **33**

Recommended Separation Distances **36**

Description

This Operator Manual contains instructions for use for the DL900, DL900 SD and DL900 SD 7 Day Holter Monitors. These Holter Monitors are battery operated solid-state monitors. The DL900 and DL900 SD Holter Monitor is designed for up to 120 hours (5 days) of continuous recording of ambulatory electrocardiograph (AECG) data. The DL900 7-Day Holter Monitor is designed for up to 168 hours (7 days) of continuous recording of ambulatory electrocardiograph (AECG) data. All have the ability to detect and record pacemaker pulses according to the appropriate criteria for Association for the Advancement of Medical Instrumentation (AAMI) pacer detection.

The DL900 Series Holter Monitors are an AAMI Type I device and are also part of a conventional AECG recording system where the ECG is recorded on a memory card that may be removed from the monitor after the recording is complete. The memory card is then placed in a card reader that is connected to the Computer Analysis System. By following the instructions provided with your Computer Analysis System, the recorded ECG data is downloaded from the memory card for analysis. Data can also be viewed by downloading the recorded information via a USB Cable.

The DL900 series Holter monitor is compatible with computers that comply with EN60950 and have an operating system of Windows XP or newer that are equipped with properly functioning and configured hardware, software, and drivers that comply with Universal Serial Bus Specification rev. 2.0, and the USB Mass Storage Class specification ver. 1.0.

Indications for Use

The DL900 Series Holter Monitors are intended for patients requiring ambulatory (Holter) monitoring. The following is a listing of the most frequent indications for use:

1. Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.
2. Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients.
3. Evaluation of patients for ST segment changes.
4. Evaluation of a patient's response after resuming occupational or recreational activities (e.g., after M.I. or cardiac surgery.)
5. Clinical and epidemiological research studies.

6. Evaluation of patients with pacemakers.
7. Reporting of time and frequency domain heart rate variability.
8. Reporting of QT Interval.

Recent DL900 Changes

Memory card technology changes continue to occur. Effective January 16, 2012, new Braemar certified SD Memory cards are available to order for existing DL900 Holter units in the field that have utilized the MMC memory card and need a replacement memory card. The replacement SD Memory Cards will include an instruction sheet. SD Memory Cards will also be used for any RMA unit that requires memory card replacement.

DL900 Phison SD Card Service Instructions

Your replacement Holter memory card is a different memory type than the card originally supplied with your monitor. Recent changes in memory technology from an older style MMC standard to the current SD memory format have resulted in slightly higher power consumption while recording. Older MMC card technology is now unavailable for commercial applications.

Braemar recommends that any recording in excess of 48 hours be performed with a new lithium battery installed at the time the recording is started. Our testing has shown typical performance as shown in the table below. Actual recording lengths can vary based upon numerous factors including the brand of battery, state of charge of the battery, age of battery, actual power consumption of the circuit board, and other factors.

Typical Running Length (Hours) with Different Sample Rates							
AAA Alkaline LR03 Average running length in number of hours.[1, 2]	**10 Bit**	128 sps	133 sps	180 sps	256 sps	512 sps	1024 sps
	3 Channel	**90**	**-**	**-**	**81**	**55**	**33**
AAA Lithium L92-FR03 Average running length in number of hours.[1, 2]	**10 Bit**	128 sps	133 sps	180 sps	256 sps	512 sps	1024 sps
	3 Channel	**120**	**-**	**-**	**118**	**82**	**-**

1. Based upon testing with an Energizer LR03-AM4 alkaline battery and an Energizer L92-FR03 lithium battery.
2. 8 bit resolution can be expected to be within 5% of 10 Bit resolution.

Monitor Components

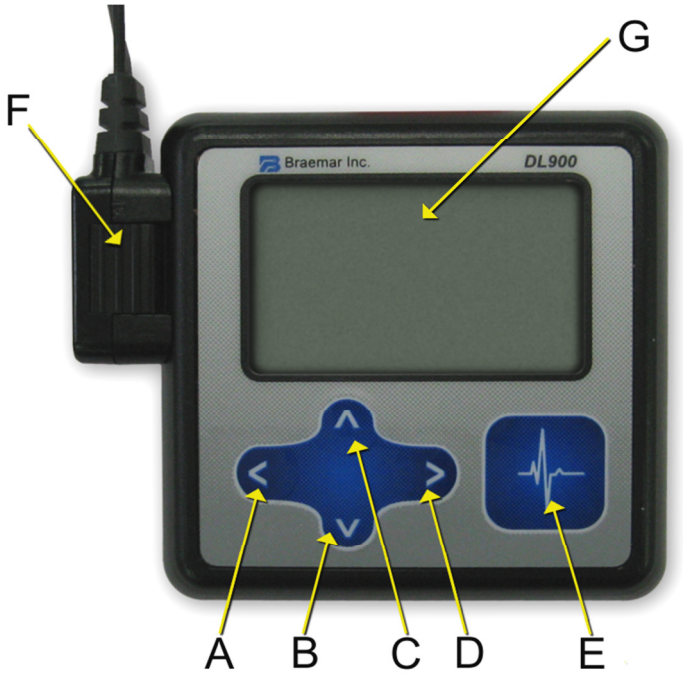

Figure 1

Figure 1 – Front view of the monitor

Letter	Description
A	Left button
B	Down button
C	Up button
D	Right button
E	Enter button
F	Patient Cable
G	Screen to display feedback from the monitor

Precautions

1. **Use only a Braemar, Inc. certified memory card for recording. Verify that you are using the correct memory card. DL900 SD Holters will have "SD" printed on the device back label.**
2. **It is very important that you observe the "Early Out" procedure. Failure to do so may result in the loss of recorded ECG (Holter) data. See Page 18.**
3. Disconnect patient leads before using a defibrillator.
4. Users must ensure that they configure the DL900 with settings compatible with their ECG analysis software.
5. False positive and false negative pacer detects may occur when using Pacer Detect.
   - False positives – may result from poor electrode connection to the patient or a large amount of electrical interference from nearby source.
   - False negatives – may occur with pacers that are bipolar because of a weak pacer pulse signal at the patient's skin.
6. When viewing the ECG data, the presence of pacemaker signals in the ECG trace should not be considered true representations of the actual pacemaker stimulus amplitude.
7. Use of rechargeable batteries is not recommended.
8. Observe local laws for disposal of alkaline batteries.
9. To avoid the possibility of corrosion damage to the monitor, do not leave batteries in the device when it is not in use.
10. To receive the best recording results, instruct patients to stay away from heavy electrical equipment or other sources of electromagnetic interference. Equipment such as electric blankets and heating pads are included in this group.
11. A minimum of 180s/s and 10 bit resolution is needed for patients weighing less than 22 lb. (10 kg.).
12. The DL900 7 Day operates at 40 Hz and is not intended for use with infants.

Additional equipment classification information as required in EN 60601-1

A. EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE
B. IPX0-Ordinary Equipment (enclosed equipment without protection against ingress of water)
C. Internally Powered Equipment
D. Mode of Operation – Continuous Operation

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician

Electrode Application

1. Connect the patient leadwire to the electrode.
2. Remove the protective backing from the electrode.
3. Apply electrode to the patient's skin.
4. Apply electrodes to match Figures 2 through 4 in this manual or as instructed by the physician.

NOTES:

- *It is recommended that trained medical personnel handle the application of electrodes.*
- *Proper preparation of the patient's skin is essential for obtaining a good ECG recording. Refer to your electrode manufacturer for instructions on skin preparation techniques.*
- *Use only good quality electrodes designed for longer term recording with a Holter monitor. All the electrodes should come from the same manufacturer.*
- *Improper connection will cause inaccuracies in the ECG.*

3-Channel (7-Lead) Electrode Placement

7 color-coded leadwires are used to create a 3-Channel ECG recording. This is a typical electrode placement. Refer to your Analysis System software and the physician for a recommended position.

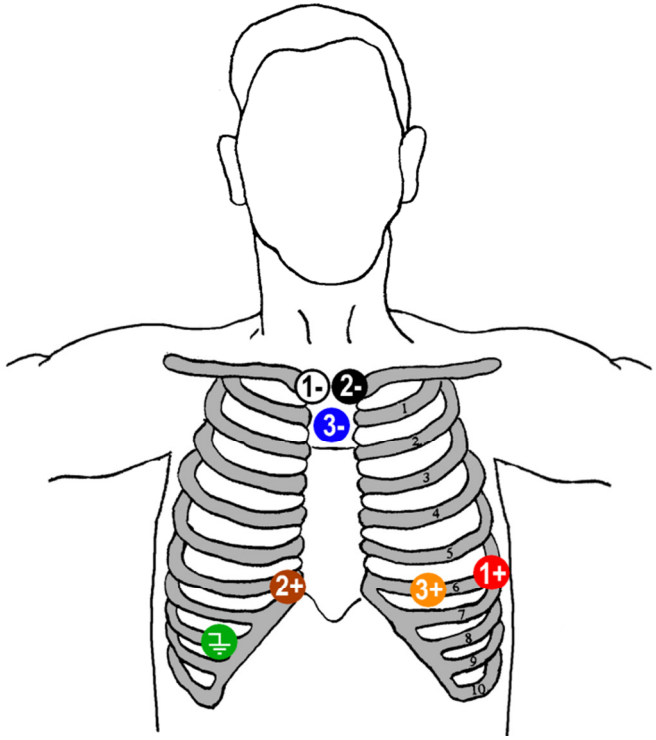

Figure 2 – 7-Lead Electrode Placement

Channel	Color	Location
1-	White	Right Manubrial border of the Sternum.
1+	Red	Left Anterior Axillary line 6th rib.
2-	Black	Left Manubrial border of the Sternum.
2+	Brown	Approximately 1 inch right of Xiphoid Process on the rib.
3-	Blue	Center of the Manubrium.
3+	Orange	Left Mid-Clavicular line 6th rib.
⏚	Green	Lower right rib margin over bone.

3-Channel (5 Lead) Electrode Placement (1st option)

5 color-coded leadwires are used to create a 3-Channel ECG recording. This is a typical electrode placement. Refer to your Analysis System software and the physician for a recommended position.

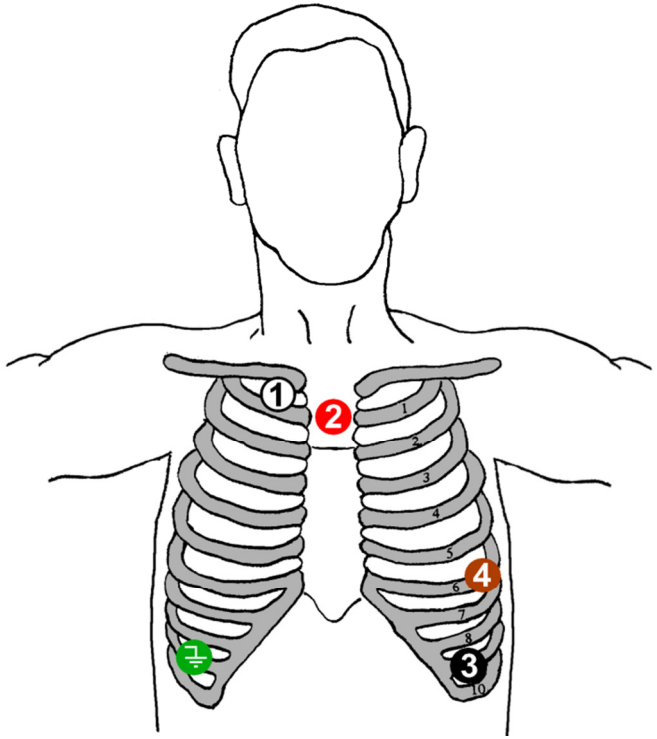

Figure 3 – 5-Lead Electrode Placement

#	Channel	Color	Location
1	3-	White	Next to the right Manubrium border on the Clavicle
2	1-, 2-	Red	Centered on the Manubrium
3	2+, 3+	Black	Lower left rib margin over bone.
4	1+	Brown	Left Anterior Axillary line on the 6th rib
5	⏚	Green	Lower right rib margin over bone.

3 Channel (5-Lead) Electrode Placement (2nd option)

5 color-coded leadwires are used to create a 3-Channel ECG recording. This is a typical electrode placement. Refer to your Analysis System software and the physician for a recommended position.

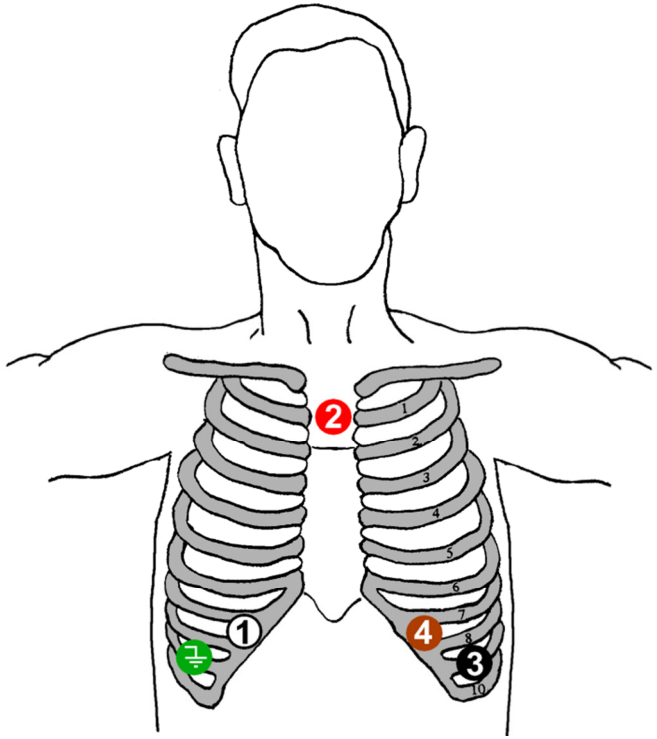

Figure 4 – 5-Lead Electrode Placement

#	Channel	Color	Placement
1	3-	White	Right side below the V1 position, at the bottom of the rib cage
2	1-, 2-	Red	Center on the Manubrium, the top of the sternum
3	2+, 3+	Black	Left side at the V5 position, on a rib
4	1+	Brown	Left side at the V3 position, on a rib
5	⏚	Green	Right side opposite V5 position.

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How to Setup and Record

1. Install the memory card. The card locks into place when fully inserted. Be sure to observe correct direction and method when inserting. Reference Figure 5 for information about memory card orientation.
2. New DL900 SD Holter Kits will contain new Braemar certified SD Cards. These SD cards are specific to the new DL900 Holter unit. The DL900 Holter unit will display a new Device Back Label with an “SD” notation to identify this Holter device.

Back Label of Monitors Originally Shipped with MMC Memory Cards

Back Label of Monitors Originally Shipped with SD Memory Cards

3. New SD cards are specifically typed and compatible with the new Holter units and are not interchangeable with existing units in the field

Original Equipment MMC Card

Service Replacement for MMC Card

Original Equipment SD Card

NOTE: The DL900 SD and DL900 SD 7 Day are only compatible with Braemar, Inc. certified memory cards. Refer to Maintenance & Service located in this manual to order a replacement.

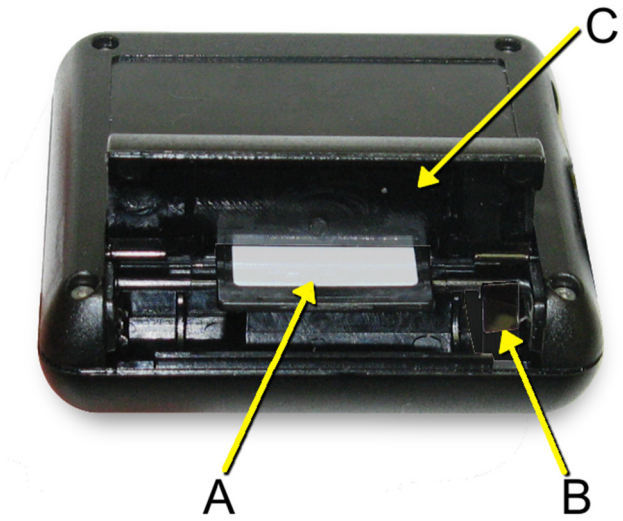

Figure 5 - Compartment

Figure 5 – Memory card installation (Bottom View)

Letter	Description
A	Memory card (Top Label Viewable)
B	Battery removal ribbon
C	Door that covers memory and battery area

4. Install a fresh AAA battery into the DL900 SD or DL900 SD 7 Day Holter. Be sure to observe the correct battery polarity. The monitor will display a splash screen: Press any key to start.

NOTES:

- *The battery should not push on the memory card. If this condition occurs, finish installing the memory card before installing the battery.*
- *An INSERT CARD message appears at the bottom of the splash screen if the memory card is not installed or installed incorrectly.*
- *Close door by pushing on the two outside edges of the battery door following the two step process below (See Figure 6).*

  1. Close the door so there is a gap at location A, and the door overhangs the case as shown in location B.

  2. Slide the door closed until the gap at location A is closed and the overhang at location B no longer protrudes.

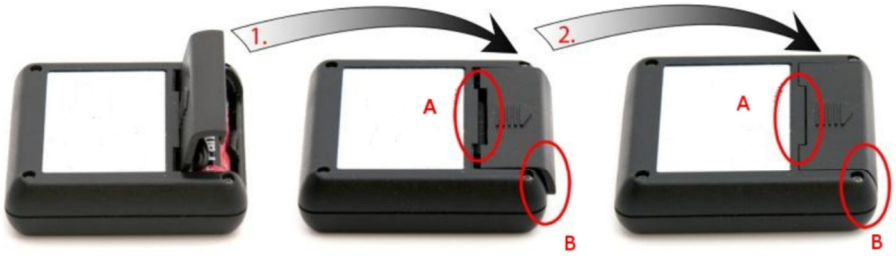

Figure 6 - Two Step Battery Door Closing Process

5. Connect the patient cable to the DL900 SD or DL900 SD 7 Day Holter. The patient should already be connected to the electrodes and patient leads.

NOTE: *Insert patient cable with the patient cable direction as shown in Figure 1. The locking clip on the cable requires a very firm push to lock it in place on the monitor. However, it only needs to be removed in the event of damage or for convenience of storage.*

6. With the splash screen shown on the LCD, press any key to advance into the menu system. The memory card is initialized (formatted) and the *Patient* screen appears.

   - **The monitor does not advance past the splash screen unless a patient cable is plugged in.** A "No Cable" message appears to indicate that a patient cable must be connected to the monitor.
   - The monitor automatically starts recording data 30 minutes after the Patient screen is displayed.
   - If the monitor does not turn on after following the steps above, refer to the Troubleshooting section.

Monitor Menu Layout and Description

Tab Screen	Layout / Description	
Patient	Used to enter the patient information.	
	Patient ID	
	First Name	
	Last Name	
	Birth Date	Format is controlled in the Date/Time tab
	Clinic ID	
CH1, 2, 3	Displays the ECG signal in real time. Pacer pulse marks and the gain setting are also displayed. Lead errors and no cable messages are also displayed when applicable.	
Lead Status	Displays the connection status of each lead to the patient.	
Start	Push the button to start the recording. Displays patient demographics if they exist. Displays "Pacer Detection ON" when pacer is enabled in the settings tab.	
Settings	The overall settings for the recording	
	Record Time	1, 6, 12, 24, 48, 72, 96, 120, (144, 196 hours; applies only to 7-day monitors)
	Pacer detection	ON or OFF
	Language	English, Spanish, Russian, German, French, Italian, Portuguese, Swedish, Polish, Dutch, Finnish, and Danish.
	Contrast	20-95%
	Sample Rate	128, 133, 180, 256, 512, 1024 s/s
	Resolution	8, 10 bit
	Save as default	Save the current settings as the default for the monitor.

Tab Screen	Layout / Description	
Date/Time	Used to set the Date/Time option.	
	Month	January – December
	Day	1 – 31 (month dependent)
	Year	1970 – 2029
	Date Format	MM/DD/YYYY, YYYY/MM/DD, DD/MM/YYYY, YYYY/DD/MM
	Hour	0 – 23
	Minute	0 – 59
	Auto DST	ON or OFF, Daylight savings time uses the USA convention
	Time Format	12 or 24 hr

About	Displays Model Name (i.e.: DL900, DL900 7 Day) Serial # Firmware/configuration Version #

NOTE: *The user interface for the DL900 SD and DL900 SD 7 Day has tabs across the top and additional settings inside each tab. Pressing the ◄ or ► buttons moves from one tab to the next. Press ▲ or ▼ to choose from the settings within that tab. If you cannot change from one tab to another, press the to save your setting. The ◄ or ► buttons are then available change from one tab to the next.*

7. Enter the *Patient ID* if desired. (16 numbers maximum)
   A. Select *Patient ID*, then press to edit.
   B. Enter the *Patient ID* number by pressing ◄, ►, ▲, or ▼ then pressing “. Repeat this process until the entire *Patient ID* number is entered. If you enter a wrong number, select *[Back]* and press .
   C. Select *OK* and press to save and exit the *Patient ID* screen. To exit without saving, select *Cancel* and press .

NOTE*: Scroll arrows indicate additional fields that are located off screen. To access these additional fields, press the ◄, ►, ▲, or ▼. The screen automatically moves to allow access to these additional fields.*

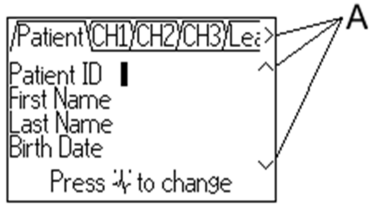

Figure 7

Figure 7 – Scroll indicator locations

Letter	Description
A	Arrows indicate more information is located off the edge of the screen.

8. Enter the *First Name* if desired. (16 characters maximum)
   A. Select *First Name*, press to edit.
   B. Enter the *First Name* by pressing ◄, ►, ▲, or ▼ then pressing . Repeat this process until the *First Name* is entered. If you enter a wrong letter, select *[Back]* and press .
   C. Select *OK* and press to save and exit the *First Name* screen. To exit without saving, select *Cancel* and press .
9. Enter the *Last Name* if desired. (16 characters maximum)
   - Follow the same steps as entering the *First Name*.
10. Enter the *Birth Date* of the patient if desired.
   - Follow the same steps as entering the *Patient ID*.
11. Enter the *Clinic ID* if desired. (16 numbers maximum)
   - Follow the same steps as entering the *Patient ID*.
12. Check that there is a good connection to the patient. Use the◄ or ► buttons to change to each screen. Check that each screen has a good ECG signal.

NOTES:

- *Figure 8 shows what lead loss message looks like for each channel. When the monitor detects lead loss the ECG displayed on the screen will not be valid.*

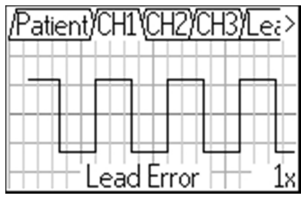

Figure 8 -Lead Loss signal

- Press the ▲ or ▼ buttons to change the gain of the monitor. The gain is displayed in the lower right hand corner of the screen.

Table 1 – Gain settings

Gain on screen	millivolt range
0.5x	+/- 5 peak-to-peak
1x	+/- 2.5 peak-to-peak
2x	+/- 1.25 peak-to-peak

- The gain setting is the same for all channels and only affects information displayed on the screen.
- The recording for all resolutions is always made at the 1x gain setting, unless the gain is changed to another setting as in Table 1.
- If *Pace Detect* is turned on, pacer pulse marks are displayed below the trace to indicate the detection of each pacer pulse.
- The monitor will “NOT” implement an auto-start recording in 30 minutes if in total lead loss, the cable is removed or all 3 channels display lead loss, as in Figure 7, unless the key is pressed.

13. Check the *Lead Status* tab for loose connections to the patient.

NOTES:

- *indicates a lead has a good patient connection.*
- *indicates a lead does not have a good patient connection.*
- *The screen displays Leads OK or Lead Error message in the lower left corner of the screen to indicate whether a good patient connection is present.*

14. Check the settings for the monitor. Use the◄ or ► buttons to change to the *Settings* screen.
    A. To make changes, press the button.
    B. Select the setting you want to change by pressing▲ or ▼.
    C. Change the value by pressing ◄ or ►.
    D. To save all changes press . There is not an option to cancel the changes made. You may also save your current settings as the **default** at the bottom of the menu. See Note on next page for operation.
    E. See Note on the next page if you cannot select all of your desired settings.

Note About Recording Length and Card Size:

- The monitor only allows you to select settings for a recording that will fit on the memory card. There is a relationship between the record time, sample rate, and resolution. By choosing a higher value for one of these parameters, you may need to choose a lower value for another. You should set the lowest variable desired first, then the second highest, then the highest.

  Example of record time, sample rate, resolution:

  You have a 512MB memory card.

  The monitor is currently set to 24 hr, 180 sps, 10 bit.

  The settings you want are 72 hr, 512 sps, 10 bit.

  The monitor will not let you achieve your final settings with a 512MB memory card because the recording will not fit on the card. You must choose which settings are more important to you. You can decrease the time to 48 hours and still maintain 512sps and 10bit. You can also decrease the resolution to 8bit and still maintain 72hr and 512sps.

- To save your changes as the default values for the monitor follow these steps:
  - Highlight *Save as default* at the bottom of the list and press the button.
  - Change the setting to *Yes*, and press the buttons.

Typical Running Length (Hours) with Different Sample Rates DL900 SD and DL900 7-Day							
AAA Alkaline IECLR3 Average running length in number of hours.[1, 2]	**10 Bit**	128 sps	133 sps	180 sps	256 sps	512 sps	1024 sps
	3 Channel	**96**	**96**	**96**	**96**	**72**[1]	**24**
AAA Lithium L92-FR03 Average running length in number of hours.[1, 2]	**10 Bit**	128 sps	133 sps	180 sps	256 sps	512 sps	1024 sps
	3 Channel	**120**	**120**	**120**	**118**	**72**	**24**

1. 72 hours at 8 bit, 48 hours 10 bit
2. Based on 1250mAH battery.
3. Note memory card size requirements.
4. 8-Bit Resolution is within 5% of 10-Bit Resolution for running length unless noted.
5. When recording for 7 days using the DL900 7-day recorder, a lithium battery must be used, and the sample rate must be set to 180 or less.

15. Check the Date and Time of the monitor. Use the◄ or ► buttons to change to the *Date/Time* screen.
    A. To change the *Date*, press the button to edit.
    B. Select the setting you want to change by pressing▲ or ▼.
    C. Change the value by pressing ◄ or ►.
    D. To save all changes press the button. To change incorrect information that was saved on a previous screen, you must finish setting the *Time* screen and re-enter the *Date* screen.
    E. Repeat steps A through D for the *Time* screen.

***NOTE**: Daylight savings time uses the USA convention.*

16. To start recording, use the◄ or ► buttons to change to the *Start* screen and press the button.
17. It is recommended that the monitor be inserted in the DL900 holster and be worn on a patient's belt or placed in the pouch and worn around the neck. A disposable one-time use pouch is also available for order.

During a recording

During recording, the DL900 displays the date, current time, time remaining for the recording, and any lead errors or cable loss if they are present.

Patient Event Marker and Reporting Symptoms

The DL900 allows an easy way for the patient to record his/her reason for pressing the button. This ensures clarity of entries by providing a list which the patient may choose from.

The medical technician or physician should provide the patient with an explanation of what is to be marked as an Event. To indicate an Event, the patient simply presses the button.

***NOTE:** Once a manual event has been activated, the patient must wait one minute to activate another manual event.*

Early-Out and real time ECG during a recording

The DL900 optionally supports an Early-Out feature that allows a trained individual to stop a recording before the selected recording time has elapsed. To initiate an Early-Out press the◄ and buttons simultaneously. If the user chooses to end the recording, observe the menu tab with the option to do so. Then select Stop Recording and press the button.

To view real time ECG from the monitor, press the ◄ or ► buttons to change to the *CH1, 2, or 3* screens. The *Lead Status* screen shows the connection status of each lead to the patient. When viewing the real time ECG, the user can return to the recording manually, or the DL900 will automatically return after 5 minutes have elapsed. Real time mode does not interrupt recording.

When the session is complete (completed by a trained medical technician) the ECG data is available for analysis.

Removal of Monitor, Battery and Patient Cable

1. Remove the electrodes from the patient.
2. Remove the battery by pulling the battery removal ribbon straight out; do not pull up. (See Figure 5, B). Properly dispose of the alkaline battery according to local laws. Lithium battery is to be removed from the monitor when the monitor is not in use.
3. Remove the patient cable by squeezing the two side latches on the head of the patient cable and pulling away from the monitor.

NOTE: *NEVER pull on the cable itself because this can easily break the wire inside the insulation. Pulling on the cable also can cause a noisy and intermittent ECG recording.*

Analyzing the ECG Data (two options)

Choose a Computer Analysis System on which the ECG analysis is to be performed. The Computer Analysis System must have special download software installed to transfer the ECG data from the memory card to the Computer Analysis System.

1. The user has two options to analyze the captured ECG data:
   - A) Memory Card: Remove the memory card from the monitor by pushing the card in until you hear a small click and the card ejects. (See Figure 5, A). Insert the memory card into the card reader of the Computer Analysis System and transfer the ECG data according to the manual for the Computer Analysis System.
   - B) USB connectivity: The user also has the option to download the recording on the memory card via USB without having to remove the card from the monitor. Start by removing the patient cable, replace it with the USB cable (P/N 350-0291-00) and confirm that the card is still in the monitor. Attach the other end of the USB cable to any available USB port on a computer. The monitor is now acting as a card reader and can be accessed similarly as any removable disk drive would be.
2. Once the data transfer is complete, remove the previous patient's name and any other information on the memory card and erase the ECG data.

NOTE*: Reinserting the flash card into the monitor, powering on the device with patient cable inserted and entering the setup menu by pressing a button will automatically erase the data from the previous patient.*

3. The memory card is now cleared of the previous data and free to be used for the next patient.

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Maintenance and Service

Cleaning

Remove the battery before cleaning the monitor. Dampen a soft cloth with mild detergent and water to clean the monitor, leadwires, and holster. Reinstall batteries and battery cover when cleaning is complete.

For best results, Braemar recommends following the ANSI/AAMI EC53 guidelines, Section 4.3.1 guidelines for cleaning our devices and cables: The device, patient leadwires and holster should be cleaned with the following materials:

- Green soap, green soap tincture (U.S. Pharmacopeia) or alcohol-free hand soap
- Sodium hypochlorite (bleach) solution 10% in water
- Isopropyl alcohol may also be used on the monitor but **may not** be used on the leadwires.

NOTE: *Use of other alcohols, acetone, AlkylDimethyl Benzyl ammonium chlorides or amethyl ammonium chloride is NOT recommended to clean the monitors. Use of alcohol or acetone on leadwires could cause the leadwires to stiffen and the insulating plastic to crack. Use of amethyl ammonium chloride (commonly found in many consumer wipes) on the monitor and holster could cause the plastic to deteriorate.*

- **Do not immerse into cleaning solutions.**
- When sterilization is required, use hospital-approved procedure for EtO, not to exceed 50°C/122°F. Frequent sterilization will reduce the useful life of cables and leadwires.
- Follow cleaning instructions exactly. Failure to follow instructions or use of other than recommended cleaning solutions may cause damage to cables, leadwires, and plastic case of the device.
- Store the cables/leads suspended when possible.
- Avoid kinking the cables/leads.

Service

If there is a problem with the monitor, review the Troubleshooting Section for a listing of problems and solutions. If additional assistance is required, contact customer support via phone, fax or e-mail listed in this manual. Call customer support before returning a monitor to make shipping arrangements.

NOTE: *There is no preventative inspection or maintenance that can be performed by the end user.*

Service Items & Accessories

Description	Part Number
Battery door	100-1775-001
Holster	100-1887-001
Pouch Disposable one-time use	100-1892-001
Patient cable 3 Channel - 5 Lead	350-0290-00
Patient cable 3 Channel - 7 Lead	350-0290-01
USB cable	350-0291-00
SD Memory Card for units shipped after January 16th, 2012	350-0315-00
Operator manual	600-0636-00
Kit,Service,DL900,Phison SD Card, instruction sheet included, units shipped prior to January 16th, 2012	800-0439-00

Troubleshooting

Symptom	Solution
No display	Check battery direction.
	Ensure patient cable is inserted completely. Then press .
	Install new battery.
Splash screen remains displayed	Check if the *INSERT CARD* message is displayed and reinstall the memory card.
Low battery message	Inspect battery compartment, clean contacts if necessary.
	Install new battery.
Battery does not last for the selected number of hours	Ensure new battery is being used.
	Ensure the memory card is Braemar, Inc. Certified.
Monitor does not run for the selected number of hours	Check that Settings screen is set for the desired number of hours.
	Memory card has only enough memory capacity to run for the number of hours which are available as valid selections in the Settings menu.
Noise artifacts on ECG signal	Ensure all electrodes are securely attached to the patient.
	Ensure patient cable is inserted completely.
	Replace the patient cable.
Defective Card Message	If multiple cards are defective, call for service.
Any Other Errors Contact Braemar	
LEAD ERROR displayed	Ensure leads are connected to the electrode and electrodes are attached to the body.
NO CABLE displayed	Ensure cable is connected properly.

The DL900 SD and DL900 SD 7 Day monitor perform a power-on self-test when the battery is installed. If the test finds a problem with the monitor, it displays an error message on the LCD. The common error codes and action are as follows:

Error Message	Number	Action
Self Test Error: Keypad failure	52	Make sure no buttons are pressed while reinserting the battery. If the problem persists, contact Braemar Customer Service for repair.
Self Test Error:	53	Repeat firmware/configuration update with a new battery. If the problem persists, contact Braemar Customer Service for repair.
Error:	203-206	Remove the SD card from the monitor, delete any .UPG files from the SD card and repeat the update process. If the problem persists, contact Braemar Customer Service for repair.
Error:	401-410	SD card error; reformat the Memory card or replace the card with a new Braemar certified SD card and reinsert the battery. If the problem persists, contact Braemar Customer Service for repair.
Any other error codes:	xxx	Remove and reinsert the battery. If the error persists, contact Braemar Customer Service for assistance and/or repair.

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Equipment Symbols

Symbol	Description
	Type B Applied Part
	Consult Manual.
CE 0086	Complies with the Medical Device Directive of the European Union.
	Waste Electrical and Electronic Equipment (WEEE) It is the responsibility of the end user to dispose of this equipment at a designated collection point for recycling.
20XX	Year of Manufacture
SN	Serial Number
REF	Catalogue Number
	Manufacturer

Manufacturer:
Braemar, Inc.
1285 Corporate Center Drive, Suite 150
Eagan, MN 55121 USA

Phone: 800.328.2719
651.286.8620
Fax: 651.286.8630
E-mail: service@braemarinc.com
Web: http://www.braemarinc.com

Authorized European Rep:
QNET BV
EC REP
Hommerterweg 286
6436 AM Amstenrade
The Netherlands

Specifications

Functional

Channels	3 channels
Resolution	8, 10 bits
Recording	Full disclosure
Download interface	USB 2.0
Sample rate	Selectable up to 1024/sec max
Frequency response	0.05 Hz to 60 Hz, @ -3 dB
Signal verification	LCD display
Pacemaker Detection	Programmable on/off

Memory

Recording time	Up to 168 hours (7 days depending on model)
Type	Flash
Model	DL900
Card size	512 MB, 1.0 GB Card

Physical

Dimensions	2.44” x 2.44” x .67” [61.98 mm x 61.98 mm x 17.02 mm]
Weight with batteries	< 2 oz [<56 g]
Enclosure	Molded plastic (UL 94V-0)
Operating position	Any orientation

Electrical

Gain settings	0.5X, 1X and 2X
Connector	20 pin
Patient cable	5 or 7 Lead

Environmental

Operating temperature	0°C to +45°C
Non-operating temperature	-20°C to +65°C
Operating humidity	10% to 95% (non-condensing)
Non-operating humidity	5% to 95% (non-condensing)

Battery

Type – (1) AAA Alkaline IEC-LR3	Life – 96 hours (4 days)
Type – (1) AAA Lithium L92-FR03	Life – 168 hours (7 days)

Warranty

1 (one) year from shipment

Electromagnetic Emissions

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The DL900 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The DL900 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Electromagnetic Immunity

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Immunity Test	IEC 60601 test level	Compli-ance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance:
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the unit is used exceeds the applicable RF compliance level above, then the unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the unit. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances

Refer to the following table for recommended separation distances between the DL900 and portable and mobile RF communications equipment.

The DL900 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the DL900 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DL900 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Note1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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